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Santé Canada
Agence de réglementation de la lutte antiparasitaire

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RE-EVALUATION DECISION

Zinc Phosphide

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Re-evaluation Decision

After a re-evaluation of the rodenticide zinc phosphide, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting continued registration of zinc phosphide products for the sale and use in Canada.

An evaluation of available scientific information found that, under proposed conditions of use, products containing zinc phosphide, do not present unacceptable risks to human health or the environment. As a condition of the continued registration of zinc phosphide uses, new risk-reduction measures must be on the labels of products containing zinc phosphide.

The regulatory approach regarding the re-evaluation of zinc phosphide was first proposed in the consultation document[1]: *Re-evaluation of Zinc Phosphide* (PACR2006-08). This Re-evaluation Decision Document[2] describes this stage of PMRA's regulatory process concerning the re-evaluation of zinc phosphide and summarizes the Agency's decision and the reasons for it. No comments were received during the consultation process. This decision is consistent with the proposed re-evaluation decision stated in PACR2006-08. To comply with this decision, registrants of products containing zinc phosphide will be informed of the specific requirements affecting their product registration(s) and of regulatory options available to them.

What Does Health Canada Consider When Making a Re-evaluation Decision?

The PMRA is re-evaluating older active ingredients and their uses to determine their continuing acceptability in relation to human health, environment and value. Zinc phosphide is one of the active ingredients to be re-evaluated during the current re-evaluation cycle. Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program*, presents the details of the re-evaluation activities and program structure.

Zinc phosphide has been re-evaluated under the Re-evaluation Program 1, which relies as much as possible on foreign reviews, typically, United States Environmental Protection Agency (USEPA) Reregistration Eligibility Decision (RED) documents. For products to be re-evaluated under Program 1, there must exist a suitable foreign review that meets the following conditions:

- it covers the main science areas, such as human health and the environment, that are necessary for Canadian regulatory decisions;
- it addresses the active ingredient and the main formulation types registered in Canada; and
- it is relevant to registered Canadian uses.

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

Based on the outcome of foreign reviews, the PMRA will propose, under Program 1, a regulatory decision and appropriate risk-reduction measures for Canadian uses of an active ingredient. In this decision, the PMRA takes into account Canadian use patterns and issues (e.g. the Federal Toxic Substances Management Policy [TSMP]). A review of the chemistry of Canadian products is also conducted.

The USEPA conducted a re-evaluation of zinc phosphide and conclusions of this re-evaluation were published in a 1998 RED. The following documents were used in the re-evaluation of zinc phosphide:

- *Amendment to the Rodenticide Cluster and Zinc Phosphide Reregistration Eligibility Decision (RED) Documents.* Federal Register, Vol. 66, No. 229. Wednesday, 28 November 2001;
- *Potential Risks of Nine Rodenticides to Birds and Nontarget Mammals: a Comparative Approach* (July 2004); and
- *Overview of the Rodenticide Comparative Ecological Assessment*(September 2004).

On the basis of health and environmental risk assessments, the USEPA concluded that zinc phosphide was eligible for reregistration with implementation of risk-reduction measures. Based on a comparison of American and Canadian use patterns, the USEPA assessments described in the 1998 RED and the other documents listed above, were considered to be an adequate basis for this Canadian re-evaluation decision.

What Is Zinc Phosphide?

Zinc phosphide is a rodenticide used to control rats, house mice, deer mice, pocket gophers, ground squirrels and meadow voles in agricultural, industrial, commercial and residential settings. It is applied by professional applicators or farm workers either by hand, burrow builder machine or hand probe (ground squirrel and pocket gopher burrow use); mechanical broadcast or by hand around each tree (orchards, nurseries, Christmas tree plantations and newly reforested areas to control deer mice and meadow voles); or placed by hand (around farm buildings, feed barns, storage sheds, poultry houses, industrial buildings or residential buildings to control rats and house mice). Appendix I lists all products containing zinc phosphide that are registered under the authority of the *Pest Control Products Act*.

❖ Health Considerations

♦ Can Approved Uses of Zinc Phosphide Affect Human Health?

Additional risk-reduction measures are required on labels containing zinc phosphide. Zinc phosphide is unlikely to affect your health when used according to the revised label directions.

Exposure through food or drinking water is expected to be minimal based on the use pattern of zinc phosphide. Exposure to zinc phosphide could occur while working as a mixer/loader/applicator or by postapplication exposure that could result in accidental

ingestion (e.g. children). No toxicological endpoints of concern were identified by the USEPA; however, some risk-reduction measures were recommended based on several occupational scenarios where inhalation of particulates and/or dusts could occur and based on scenarios that could result in accidental ingestion by children or pets.

The USEPA concluded that zinc phosphide was unlikely to affect human health provided that risk-reduction measures were implemented. These conclusions were considered to be applicable to the Canadian situation, and equivalent risk-reduction measures are required.

❖ Environmental Considerations

♦ What Happens When Zinc Phosphide Is Introduced Into the Environment?

Zinc phosphide is toxic to non-target organisms; therefore, additional risk-reduction measures need to be observed.

Non-target organisms (e.g. birds, mammals, insects, aquatic organisms and terrestrial plants) may be exposed to zinc phosphide in the environment. Environmental risk is assessed by the risk quotient method, in which a risk quotient (RQ) is calculated as the ratio of the estimated environmental concentration to the relevant effects endpoint of concern. The resulting RQs are compared to corresponding levels of concern (LOCs). An RQ less than the level of concern is considered as a low risk to non-target organisms, whereas, a risk quotient greater than the level of concern indicates some degree of risk.

The continued registration of zinc phosphide is acceptable provided risk-reduction measures to further protect the environment are implemented.

Measures to Minimize Risk

Labels of registered pesticide products contain specific directions for use, which include risk-reduction measures to protect human and environmental health. These directions must be followed by law. As a result of the re-evaluation of zinc phosphide, further risk-reduction measures are proposed in addition to those already identified on existing product labels containing zinc phosphide. These additional measures are summarized as follows.

- **Human Health**
  - To protect handlers: additional protective equipment
  - To protect workers and bystanders: use will be limited to certified pest control operators, farmers and persons authorized in government-approved pest control programs
  - To protect children and pets: bait must be placed in bait stations or in locations not accessible to children, pets or livestock in residential settings or in other areas where children may be present

- **Environment**
    - To protect non-target sensitive terrestrial birds and mammals including species at risk: specific statements regarding burrows are required

Appendix II lists all required label amendments for commercial products and Appendix III lists all required label amendments for restricted products. A submission to implement label revisions will be required within 90 days of this re-evaluation decision.

Other Information

Any person may file a notice of objection[3] regarding this decision on zinc phosphide within 60 days from the date of publication of this Re-evaluation Decision Document. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the PMRA's website (Requesting a Reconsideration of Decision, www.pmra-arla.gc.ca/english/pubreg/reconsideration-e.html), or contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra_infoserv@hc-sc.gc.ca).

[3] As per subsection 35(1) of the *Pest Control Products Act*.

Appendix I Current Canadian Registered Products Containing Zinc Phosphide as of 1 April 2007

Registrant	Registration Number	Guarantee	Product Name	Formulation Type	Class
Bartlett, N.M. Inc.	8024	2%	Bartlett Waxed Mouse Bait	Particulate	Commercial
Bell Laboratories Inc.	14240	2%	ZP Rodent Bait	Pellets	Commercial
Hacco Inc.	16122	2%	Clean Crop Rodent Bait	Granular	Commercial
Hacco Inc.	21838	2%	Clean Crop Rodent Pellets	Pellets	Commercial
Hacco Inc.	24795	2%	Burrow Oat Bait	Granular	Commercial
Maxim Chemical International Ltd.	27358	2%	ZIP RTU Bait	Granular	Commercial
Bell Laboratories Inc.	15368	10%	ZP Tracking Powder	Powder	Restricted
Bell Laboratories Inc.	19808	80%	Technical Zinc Phosphide	Dust / Powder	Technical
Hacco Inc.	25204	82%	Zinc Phosphide 82 Technical	Dust / powder	Technical

Appendix II Label Amendments for Commercial Products Containing Zinc Phosphide

NOTE: This appendix does not identify all label requirements for individual end-use products such as first aid statements, disposal statements, precautionary statements and supplementary personal protective equipment that may be required. Additional information on labels for currently registered products should not be removed unless it contradicts information in this appendix.

Canadian commercial end-use product labels must be amended to include the following to further protect human health and the environment.

In order to ensure that use of commercial end-use products is limited to use by certified pest control operators, farmers and persons authorized in government-approved pest control programs, the labels must be modified to include the following statement on the principal panel of the label:

> "Only to be used by certified pest control operators, farmers and persons authorized in government-approved pest control programs."

To protect handlers, children, pets, and livestock from accidental ingestion, the labels of all commercial end-use products containing zinc phosphide must be modified to include the following statements:

- In the **PRECAUTIONS** section of the label,

"KEEP OUT OF REACH OF CHILDREN, PETS AND LIVESTOCK. Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Wash skin thoroughly with soap and water after handling. Wash contaminated clothing, separately from other laundry, with soap and hot water before reuse. Users should remove clothing immediately if pesticide gets inside. Then wash skin thoroughly and put on clean clothing. Chemical-resistant gloves must be worn when disposing of dead rodents, unconsumed bait and empty containers."

"All handlers, including loaders and applicators, must wear a long-sleeved shirt, long pants, shoes plus socks and chemical-resistant gloves. In addition, persons loading pellets or bait into mechanical ground equipment or loading/applying with handpushed or hand-held equipment, must wear a NIOSH-approved particulate-filter respirator and protective eyewear."

- In the **FIRST AID** section of the label,

"For all cases of human ingestion, immediately notify a physician or poison control centre."

"If pet or livestock poisoning suspected, immediately contact a veterinarian."

- In the **STORAGE** section of the label,

"Store in a cool, dry place away from other chemicals and food or feed. Store product not in use, in original container, in a secure location inaccessible to children and non-target animals. "

For commercial zinc phosphide end-use products that can potentially be used in residential settings (e.g. to control house mice or rats) or in other areas where children may be present (e.g. parks) the end-use product labels must be modified to include the following statement:

- In the **USE LIMITATIONS** section of the label,

"Bait MUST either be placed in tamper-resistant bait stations or in locations not accessible to children, pets or livestock."

To ensure safe use of this product, tamper-resistant bait stations must have the following characteristics:

- constructed of high-strength material (e.g. metal or injection moulded plastic) and resistant to destruction by children and non-target animals;
- entrance designed so that children and non-target animals cannot reach the bait;
- internal structure that prevents bait from being shaken loose;
- access panel that fastens securely and locks (e.g. metal screw or padlock);
- capable of being securely fastened to a surface (e.g. nailed down); and
- clearly labelled: WARNING POISON."

For commercial zinc phosphide end-use products that are registered for ground squirrel control, to further protect non-target organisms including species at risk:

- In the **USE RESTRICTIONS** section of the label,

"Apply to burrows occupied by ground squirrels only. DO NOT apply to unoccupied burrows."

"Applicators of zinc phosphide should observe the potential treatment area before treating burrows, to confirm the presence of activity of ground squirrels and to ensure there is no evidence of species at risk activity or presence in burrows."

"For information on species at risk in your area, contact your provincial or federal wildlife officials."

Appendix III Label Amendments for Restricted Products Containing Zinc Phosphide

NOTE: This appendix does not identify all label requirements for individual end-use products such as first aid statements, disposal statements, precautionary statements and supplementary personal protective equipment that may be required. Additional information on labels for currently registered products should not be removed unless it contradicts information in this appendix.

Canadian restricted end-use product labels must be amended to include the following to further protect human health and the environment.

To protect handlers, children, pets and livestock from accidental ingestion, the label of the restricted class end-use product containing zinc phosphide must be modified to include the following statements:

- In the **PRECAUTIONS** section of the label,

"KEEP OUT OF REACH OF CHILDREN, PETS AND LIVESTOCK. Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Wash skin thoroughly with soap and water after handling. Wash contaminated clothing, separately from other laundry, with soap and hot water before reuse. Users should remove clothing immediately if pesticide gets inside. Then wash skin thoroughly and put on clean clothing. Chemical-resistant gloves must be worn when disposing of dead rodents, unconsumed bait and empty containers."

"All handlers must wear a long-sleeved shirt, long pants, shoes plus socks, chemical-resistant gloves and a NIOSH-approved particulate-filter respirator and protective eyewear."

- In the **FIRST AID** section of the label,

"If pet or livestock poisoning suspected, immediately contact a veterinarian."

- In the **STORAGE** section of the label,

"Store in a cool, dry place away from other chemicals and food or feed. Store product not in use, in original container, in a secure location inaccessible to children and non-target animals. "

- In the **USE LIMITATIONS** section, the following statement must be removed:

"ZP TRACKING POWDER must be placed in locations not accessible to children, pets, domestic animals or wildlife or in tamper-resistant bait boxes." and must be replaced with the following:

"ZP TRACKING POWDER must be placed in locations not accessible to children, pets, livestock or non-target wildlife."

- For the restricted class products containing zinc phosphide (i.e. tracking powder), the **USE LIMITATIONS** section of the end-use product label must be revised from:

"Do no apply tracking powder along walls, in corners, or in open-floor areas or on rafters of rooms in which food or feed is handled or stored."

to the following:

"In rooms in which food or feed is handled or stored, DO NOT apply tracking powder along walls, in corners, on open-floor areas or on rafters."